UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MEDEVA PHARMA SUISSE, A.G., and PROCTER & GAMBLE PHARMACEUTICALS, INC.	:	Civil Action No. 3:07-CV-05165 (FLW)(TJB)
Plaintiffs,	:	
	:	
-vs-	:	
ROXANE LABORATORIES, INC.	:	
Defendant.	:	

DEFENDANT'S MEMORANDUM OF LAW IN SUPPORT OF APPEAL FROM THE MAGISTRATE JUDGE'S NOVEMBER 30, 2009 LETTER ORDER

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INTRODUCTION

Defendant Roxane Laboratories, Inc. ("Roxane") appeals from the Letter Order dated November 30, 2009 (D.I. 119, Exhibit A to the Declaration of Kathryn Jones ("Jones Decl."), submitted herewith), by which the Magistrate Judge ordered that Roxane provide the Court no less than 45 days' written notice before it launches its generic drug product that is the subject of the litigation. The Magistrate Judge erred in concluding that requiring Roxane to provide such notice was within the scope of the Court's discretion to manage matters of docket control and scheduling. This pre-launch notice requirement is not a docket management device, but is instead effectively either an unauthorized extension of the statutory 30-month stay or a 45-day temporary restraining order against Roxane's marketing of an FDA-approved product. Roxane is aware of no authority that permits the Court to use its discretion over scheduling matters as a basis either to extend the 30-month stay or to issue a TRO. The Court's Order should be vacated.

FACTUAL BACKGROUND

A. The Case

This is a patent infringement case, grounded on Roxane's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic equivalent of the drug "Asacol," which is indicated for ulcerative colitis. Plaintiff P&G markets Asacol in the United States, and is licensed under U.S. Patent No. 5,541,170 ("the '170 patent"), which is owned by plaintiff Medeva Pharma Suisse AG. The case is governed by the Hatch-Waxman Act, and was precipitated by Roxane's filing of its ANDA containing a "Paragraph IV" certification that the '170 patent was invalid or would not be infringed by Roxane's marketing of its proposed drug product. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Plaintiffs filed suit within the requisite 45 days on October 26, 2007. Under the Hatch-Waxman Act, plaintiffs' timely filing of this lawsuit automatically placed in effect a stay of 30 months, during which the FDA cannot finally approve Roxane's product. 21 U.S.C. § 335(j)(5)(B)(iii). At the end of the 30-month stay, absent some action by the Court, and if Roxane's ANDA is otherwise approvable, the FDA will approve Roxane's application. The 30-month stay in this case expires on March 14, 2010.

B. P&G's Request for Notice of Roxane's Intent To Launch its Product

At the October 19, 2009 conference before Magistrate Judge Bongiovanni, the parties expressed their mutual desire to have a trial as quickly as possible. Plaintiffs asked for a trial before the expiration of the 30-month stay. Alternatively, they sought Roxane's consent for an extension of the stay pending trial and a decision on the merits. (D.I. 111, Jones Decl., Exhibit B, Conference Tr. 11:21-12:3.) The Magistrate Judge then suggested that Roxane consider providing plaintiffs with 30 days' notice before launching its proposed drug product. Plaintiffs responded by requesting a "sixty-day prior notice if [Roxane] intend[s] to launch after the expiration of the automatic stay so [Plaintiffs] have time to bring [their] permanent injunction papers." (*Id.* at 16:10-14.)

Roxane offered to compromise by providing plaintiffs with 45 days' notice of its intention to launch, so long as plaintiffs agreed to provide the same amount of notice should they choose to file a "citizen's petition" with the FDA directed to Roxane's proposed product. (Jones Decl., Exhibit C.) Roxane proposed this compromise because of the commercial harm that could result if plaintiffs knew for certain when Roxane intended to launch, and filed a groundless citizen's petition on the eve of that launch in order to delay it. *See* discussion *infra*. Plaintiffs refused this compromise and insisted on a one-sided solution that protected their commercial interests by allowing them 45 days to seek a preliminary injunction, but refused Roxane the opportunity to prepare a response to a citizen's petition that would significantly delay its market entry.

On November 30, 2009, Magistrate Judge Bongiovanni ordered that the "discovery schedule is hereby amended to require that Roxane provide the Court no less than forty-five (45) days written notice before (a) marketing, offering to sell or selling the generic drug at issue in this litigation or (b) allowing or otherwise authorizing any other party to market, sell or offer to sell the generic product at issue in this litigation." The Magistrate Judge further stated that this requirement was "within its sound discretion to manage matters of docket control and scheduling" so that it would have a "reasonable amount of time to consider any application for preliminary injunctive relief." (D.I. 119, Jones Decl., Exhibit A).

ARGUMENT

The Magistrate Judge's decision is a non-dispositive ruling that must be reversed if it is "clearly erroneous" or "contrary to law." Fed. R. Civ. P. 72(a). The decision here is outside the scope of the Court's authority, and therefore should be reversed.

A. The Court Does Not Have Authority To Impose a Notice Requirement

1. The Notice Requirement Is Not a Docket Management Issue

Neither plaintiffs nor the Magistrate Judge have cited any authority to support the proposition that the Court has discretion to order a notice period prior to the launch of a generic product. In the Letter Order, the Magistrate Judge cited *Alaska v. Boise Cascade Corp.*, 685 F.2d 810, 817 (3d Cir. 1982), which states unremarkably that the Court has discretion to "manage matters of docket control and scheduling." In *Boise Cascade*, the court was deciding an appeal based on the claim that, *inter alia*, the Magistrate Judge had unduly limited the appellants' opportunity to develop and present their case by providing too little time for discovery and trial preparation. The court denied the appeal and held that "matters of docket control and conduct of discovery are committed to the sound discretion of the district court." *Id.* at 817. Roxane does not dispute the Court's discretion to manage such scheduling issues, but imposing a commercially damaging burden on Roxane to provide 45 days' notice is not a scheduling issue. If Roxane makes its marketing decision later than 45 days before the expiration of the 30-month stay, the notice period is in effect either an extension of the stay or a temporary restraining order, entered without plaintiffs even attempting to meet the stringent criteria for such relief. Effectively enjoining Roxane's otherwise lawful commercial activities is not a matter of docket control or discovery scheduling.

2. P&G Has Not Met the Requirements for Extending the 30-Month Stay

If the date of Roxane's marketing decision is less than 45 days from the end of the 30-month stay, then the notice provision has the effect of extending the stay. The criteria for extension of that stay, however, are statutory, and do not include docket management. Specifically, the Court has the discretion to extend the 30-month stay only "if either party to the action failed to reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii).

The Federal Circuit has interpreted this provision to mean that trial courts "may shorten or extend the thirty-month statutory period based on the parties' uncooperative discovery practices before the court." *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346, 1350 (Fed. Cir. 2009). Plaintiffs have not attempted to and cannot meet the burden required under this standard. Roxane has expedited the action at every opportunity. In fact, it has been plaintiffs that have delayed discovery. Roxane completed its production of documents in January 2009. Since that time, plaintiffs have produced approximately 120,000 pages. (D.I. 111, Jones Decl., Exhibit B, Conference Tr. 17:13-16.) Despite plaintiffs' dilatory tactics with respect to discovery, Roxane is still prepared to go to trial in March 2010, as plaintiffs request. The facts here do not support any argument that Roxane has failed reasonably to cooperate in expediting the action. Indeed, Roxane has no incentive to delay the action while P&G has every reason to delay the action and take advantage of every last day of the 30-month stay.

The fact that the 30-month stay may expire before trial or before decision does not justify an extension of the stay. Courts have noted that "legislators were aware of the potential length of time it takes to resolve patent litigation, yet a stay intended to coincide precisely with that period was rejected." *Minnesota Mining & Manufacturing Co. v. Alphapharma Pty. Ltd.*, No. CIV. 99-13 MJDLGL, 2002 WL 1299996 at *3 (D. Minn. March 8, 2002), *citing Zeneca Ltd. v. Pharmachemie B.V.*, 16 F. Supp. 2d 112, 116 (D. Mass. 1998). In both those cases, the court held that if the branded pharmaceutical company wanted to prevent generic entry beyond the expiration of the stay, it had to seek and obtain a preliminary injunction.

3. P&G Has Not Met the Requirements for a Temporary Restraining Order or Preliminary Injunction

Not only is there no justification for extending the 30-month stay, plaintiffs have not met the requirements for what is effectively a 45-day temporary restraining order. The requirements for a TRO are like those of a preliminary injunction. *W & D Ships Deck Works v. United States*, 39 Fed. Cl. 638, 647 (Fed. Cl. 1997); *see also National Football League Prop., Inc. v. Coniglio*, 554 F. Supp. 1224, 1226 (D.D.C. 1983). Plaintiffs must satisfy the familiar four-part test: "(1) reasonable likelihood of success on the merits; (2) irreparable harm; (3) balance of hardships tipping in its favor; and (4) the impact of the injunction on the public interest." *Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 681 (Fed. Cir. 1990). In patent infringement actions, the patentee must establish infringement by the defendant. *Conair Group, Inc. v. Automatik Apparate-Maschinenbau GmbH,* 944 F.2d 862, 865-66 (Fed. Cir. 1991) ("Demonstrating a probability of success on the merits includes the requirement that the patentee make a showing of a likelihood of proving infringement."). Roxane contests infringement, and nothing in this record suggests that plaintiffs have established or could establish that Roxane's product is within the scope of the only asserted claim of the '170 patent.

In addition, Fed. R. Civ. P. 65 permits a TRO only for 14 days with a single 14 day extension. Nothing in the rules provides a court with discretion to enter a 45-day TRO, which is exactly what the Magistrate Judge's Order accomplishes.

B. Providing Pre-Launch Notice to P&G Will Prejudice Roxane

Roxane recognizes, of course, the Court's interest in the orderly disposition of the issues in this case, and understands that the investment in time and resources to resolve a preliminary injunction would be pointless if Roxane had no intention of marketing its product at the time the proceedings are brought. The problem with the notice requirement, however, is the tremendous and inequitable commercial advantage it provides to plaintiffs. That advantage stems from the weapon that is available to branded drug producers—the citizen's petition.

According to 21 C.F.R. § 10.30, anyone may submit a citizen's petition to the FDA to request that FDA issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action. The FDA is then required to provide a response within 180 days of receipt of the petition. 21 C.F.R. § 10.30(e)(2). If a citizen's petition is filed with respect to a generic drug product that has not yet been approved, the FDA will typically withhold final approval until it has decided the citizen's petition.

Branded pharmaceutical companies have taken advantage of the citizen's petition process to delay generic competition. In fact, branded pharmaceutical companies abused the citizen's petition process to the extent that Congress enacted certain amendments to the Food, Drug and Cosmetic Act to attempt to deal with the abuses. *See* Food and Drug Amendments Act of 2007 § 914(a). Comments from its legislative history illustrate the extent of this abuse:

> While this citizen petition process was put in place for a laudable purpose, unfortunately in recent years it has been abused by frivolous petitions submitted by brand name drug manufacturers (or individuals acting on their behest) whose only purpose is to delay the introduction of generic competition.

153 Cong. Rec. S64 (daily ed. Jan, 4, 2007) (statement of Sen. Kohl). Branded pharmaceutical companies have further abused the citizen-petition process by waiting to file their petitions until just before the FDA is ready to approve the ANDA. This last-minute filing results in the maximum possible delays in approval for the ANDA product. One of the purposes of the recent amendments was to prevent this "gaming of the system." *Id.*[1]

Congress also concluded that the majority of branded pharmaceutical companies' citizen's petitions were not meritorious. In fact, 95% of the citizen's petitions for which the FDA had reached a decision between 2003 and 2007 were found to be baseless. Of these, almost half were filed less than six months prior to the entry date of the generic drug. All of these "eleventh hour" petitions were found to be without merit, and all caused unnecessary delays in generic market entry. *Id.*

If Roxane is required to provide plaintiffs with 45 days' notice prior to the launch of its generic product, P&G will be in a position to time the filing of a citizen's petition to create the maximum possible delay, for example, by filing on the 44th day. This filing might well result in a delay in market entry for Roxane's product of up to 180 days. Effectively, this delay amounts to either an unjustified extension of the 30-month stay or the imposition of a preliminary injunction without plaintiffs having to meet their burden for establishing their entitlement to either.

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[1] The 2007 Amendments include additional certification requirements that attempt to reduce the incidence of abuse of the citizen's petition process. The process, however, is essentially unchanged.

The potential prejudice to Roxane is more than simply having to wait to launch. Branded pharmaceutical companies sometimes use the additional period of market exclusivity garnered by a meritless citizen's petition to switch the market to a related, patent-protected "follow on" drug product. In the weeks or months it takes the FDA to reject the meritless petition, the brand company "cannibalizes" the market for the generic product by switching doctors and patients to the new, patent-protected product. The net result is a diminished market for the generic product. Here, P&G has recently received FDA approval for a new 800 mg Asacol formulation. A 45-day notice period, with an additional period of exclusivity obtained through a baseless citizen's petition, could substantially damage the market for Roxane's 400 mg product.

As the foregoing discussion makes clear, the imposition of the 45-day notice period will permit plaintiffs to orchestrate the filing of a citizen's petition to have its maximum delay effect. This delay will cause great uncompensated-for harm to Roxane.[2] The notice requirement thus creates a tremendous unjustified commercial advantage for P&G.

C. Roxane Will Consent to a Notice Requirement in Exchange for Plaintiffs' Providing Similar Notice of Potential Citizen's Petition

Recognizing that the Court should not be in the position of having to deal with a preliminary injunction motion that might be unnecessary, Roxane offered to accept the 45-day notice requirement, if plaintiffs would agree with a similar notice period for the filing of a citizen's petition so that Roxane could be prepared to deal with it as soon as it is filed. Such an arrangement is fair to everyone. If Roxane decides to go to market before a decision on the merits, it would so advise plaintiffs and the Court, and plaintiffs could seek preliminary relief in the appropriate forum, i.e., the Court, rather than using the last-minute citizen's petition route to bypass the requirements for a preliminary injunction. Roxane's offer still stands.

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[2] If plaintiffs brought a successful application for a preliminary injunction, they would at least have to post a substantial bond to cover the possibility of not prevailing on the merits.

CONCLUSION

Neither the Court nor plaintiffs have cited any authority that supports the Court's decision to require Roxane to provide notice of when it will launch its commercial product. The imposition of a notice requirement without imposing such a requirement on plaintiffs is prejudicial to Roxane and unfair. The Magistrate Judge's order requiring Roxane to provide notice of its launch date without any reciprocity from plaintiffs should be vacated.

Respectfully submitted,

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